

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to care facility pharmacy practice

The Board of Pharmacy hereby amends Chapter 10, “Controlled Substances,” and Chapter 23, “Long-Term Care Pharmacy Practice,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 124.301, 124.306, 124.308, 155A.2, 155A.13, 155A.15, 155A.21, 155A.27, 155A.28, 155A.33, 155A.35 and 155A.36.

Purpose and Summary

Pursuant to Iowa Code section 17A.7(2), the Board conducted an overall review of Chapter 23 of the Board’s administrative rules. These amendments update language for consistency, remove redundancy, combine and condense rules where appropriate, and clarify prescription requirements for controlled substances to be consistent with federal regulations. The amendment in Chapter 10 updates a cross reference.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on December 20, 2017, as **ARC 3511C**.

The Board received numerous comments related to several amendments. Comments were received in opposition to the requirements that a pharmacy’s policies and procedures include policies related to automatic stop orders and methods to ensure that drug containers are labeled properly and are not in a state of disrepair. The Board rejected these comments as the rule simply requires that the pharmacy have a policy related to these areas, but does not direct what that policy says. One comment suggested that the Board change the term “care facility” to “care center,” but the Board declined to make this change as other chapters of administrative rules use the term “care facility.” One comment proposed to expand the authority of care facilities to administer all vaccinations pursuant to physician-approved facility policy, without a patient-specific medication order. The administration of influenza or pneumococcal immunizations in a care facility pursuant to facility policy and absent a patient-specific medication order is specifically authorized in Medicare regulations. Medicare regulations do not authorize such administration of all immunizations in this manner.

The Board made changes to three amendments based on the comments it agreed with. Rule 657—23.3(124,155A), related to patient freedom of choice, is further amended to defer to the rules of the Department of Inspections and Appeals with regard to the patient’s right to choose a physician and pharmacy when residing in a care facility. Subrule 23.9(3) is further amended to clarify that an agent agreement between a nurse in a care facility and a prescribing practitioner for the purpose of the transmission of a prescription specifically applies to the transmission of a controlled substance prescription in compliance with guidance from the Drug Enforcement Administration (DEA). Subrule 23.21(2) is further amended to better describe a pharmacy’s role and responsibility in operating a DEA-compliant collection receptacle in a care facility.

Adoption of Rule Making

This rule making was adopted by the Board on May 23, 2018.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 25, 2018.

The following rule-making actions are adopted:

ITEM 1. Amend rule 657—10.28(124) as follows:

657—10.28(124) Schedule II medication order. Schedule II controlled substances may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.18(124,155A) 657—23.9(124,155A), as applicable.

ITEM 2. Amend **657—Chapter 23**, title, as follows:

LONG-TERM CARE FACILITY PHARMACY PRACTICE

ITEM 3. Rescind rule 657—23.1(155A) and adopt the following **new** rule in lieu thereof:

657—23.1(155A) Purpose and scope. The purpose of this chapter is to identify the minimum standards for licensed pharmacies in this state providing pharmacy services to care facilities.

ITEM 4. Rescind rule 657—23.2(124,155A) and adopt the following **new** rule in lieu thereof:

657—23.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

“*Authorized collection program*” means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at www.deadiversion.usdoj.gov/drug_disposal.

“*Care facility*” or “*facility*” means:

1. A facility licensed by the Iowa department of inspections and appeals under Iowa Code chapter 135C or 135H;
2. A hospital-based long-term care unit certified under 42 CFR, Part 483, Subpart B;
3. An inpatient hospice certified under 42 CFR, Part 418;
4. A group living facility wherein health care-related services are provided by the facility; or
5. A health care facility registered with the board under Iowa Code chapter 124.

“*Care facility pharmacy*” or “*provider pharmacy*” means a pharmacy that provides pharmacy services to a care facility.

“Consultant pharmacist” in a care facility means an Iowa-licensed pharmacist who is responsible for developing, coordinating, and supervising pharmaceutical services in a care facility on a regularly scheduled basis.

“DEA” means the United States Department of Justice, Drug Enforcement Administration.

“Medication order,” as used in these rules, means an order from a practitioner or the practitioner’s authorized agent for administration of a drug or device. For purposes of this chapter, “medication order” includes a prescription.

“Provider pharmacist” means a pharmacist licensed to engage in the practice of pharmacy who is employed by or contracted to a care facility pharmacy or a provider pharmacy and who is responsible for supervising the accurate dispensing and proper delivery of drugs and devices to a care facility located within this state. These services shall include, at a minimum, proper medication labeling, storage, transport, record keeping, and prospective drug utilization review in compliance with all federal and state laws and regulations.

“Unit dose dispensing system” means a drug distribution system utilizing unit dose packaging.

ITEM 5. Amend rule 657—23.3(124,155A) as follows:

657—23.3(124,155A) Freedom of choice. Pursuant to 657—subrule 8.11(5) 8.11(2), no pharmacist or pharmacy shall participate in any agreement or plan that infringes on any resident’s right to freedom of choice ~~as to the provider of pharmacy services as described in rules of the department of inspections and appeals. A resident in a long-term care facility shall have a choice of long-term care pharmacy so long as the pharmacy’s drug delivery system provides for the timely delivery of drugs compatible with the established system currently used by the facility. Determination of compatibility may consider medication administration, accessibility, and payment system.~~

ITEM 6. Amend rule 657—23.4(124,155A) as follows:

657—23.4(124,155A) Responsibilities. The pharmacist in charge and staff pharmacists in any pharmacy providing pharmaceutical services to ~~long-term~~ care facility patients shall share responsibility for:

1. ~~Providing~~ Dispensing drugs pursuant to a medication order for an individual resident; that are properly labeled for that resident, as addressed in rule 657—22.1(155A) or 657—23.13(124,155A) and packaged in a manner consistent with the facility’s established drug delivery system and in compliance with applicable board rules for the drug delivery system.

2. ~~Dispensing drugs for residents of long-term care facilities consistent with the drug distribution system described in the facility’s policies and procedures.~~

3. 2. Affixing labels to each container of drugs for residents in ~~long-term~~ care facilities, in compliance with rule 657—22.1(155A), 657—Chapter 22 or rule 657—6.10(126,155A), 657—23.13(124,155A), or 657—23.14(124,155A).

4. 3. Maintaining records of all transactions of the ~~long-term care pharmacy~~ as may be required by law and maintaining accurate control over and accountability for all drugs and prescription devices.

5. 4. Complying with a drug recall procedure, established pursuant to rule 657—8.3(155A), that protects the health and safety of residents ~~including immediate discontinuation of any recalled drug or device and subsequent notification of the prescriber and director of nursing of the facility.~~

6. 5. Providing 24-hour emergency service either directly or by contract with another pharmacy.

7. 6. ~~Reviewing patient profiles to ensure the appropriateness of therapy for that resident and the compatibility of the drug and dosage for that resident when processing new medication orders. Conducting prospective drug use review pursuant to rule 657—8.21(155A) and subrule 23.5(1).~~

8. 7. Providing sufficient and accurate information to facility staff regarding the appropriate administration and use of all dispensed drugs and devices.

9. 8. Communicating with the consultant pharmacist and the facility staff regarding concerns and resolution thereof.

ITEM 7. Amend rule 657—23.5(124,155A) as follows:

657—23.5(124,155A) Emergency drugs. A supply of emergency drugs may be provided by one or more ~~long-term care provider~~ pharmacies to the facility pursuant to rule 657—22.7(124,155A).

23.5(1) No change.

23.5(2) Other emergency drugs and devices. In addition to ~~one or more~~ emergency boxes or ~~stat drug boxes~~ drug supplies, a ~~long-term care facility~~ staffed by one or more persons licensed to administer drugs may maintain a stock of intravenous fluids, irrigation fluids, heparin flush kits, medicinal gases, sterile water and saline, and prescription devices. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the consultant pharmacist and the medical director and director of nursing of the facility.

ITEM 8. Rescind and reserve rule **657—23.6(124,155A)**.

ITEM 9. Amend rule 657—23.7(124,155A) as follows:

657—23.7(124,155A) Policies and procedures. Pursuant to rule 657—8.3(155A), each pharmacy shall have policies and procedures related to all aspects of the pharmacy's packaging and dispensing responsibilities to the residents of ~~the long-term~~ a care facility. The policies and procedures shall be maintained at the provider pharmacy and shall be available to the facility and the consultant pharmacist. Policies and procedures shall include, at a minimum:

1. Methods used to dispense and deliver drugs and devices to the facility in a timely fashion;
2. Proper notification to the facility when a drug or device is not readily available;
3. Proper labeling requirements to meet the needs of the facility and which are consistent with state and federal laws and regulations;
4. Appropriate drug destruction or return of unused drugs, or both, consistent with state and federal laws and regulations.
5. An automatic stop order policy to ensure that drug orders are not continued inappropriately.
6. Methods to ensure that all discontinued, outdated, deteriorated, or improperly labeled drugs and all containers with worn, illegible or missing labels are disposed of so as to render them unusable and protected from unauthorized possession or use.

ITEM 10. Amend rule 657—23.9(124,155A) as follows:

657—23.9(124,155A) Medication orders. Drugs and prescription devices may be dispensed only upon orders of an authorized prescriber or authorized pharmacist as part of a collaborative drug therapy management protocol pursuant to rule 657—39.13(155A).

23.9(1) Requirements for noncontrolled substances. New medication orders transmitted to the pharmacy for ~~drugs for residents of the facility~~ noncontrolled substances shall, at a minimum, contain resident name, drug name and strength, directions for use, date of order, and name of prescriber. ~~Orders for Schedule II controlled substances shall comply with the requirements of rule 657—23.18(124,155A).~~

23.9(2) Abbreviations Requirements for controlled substances. ~~Abbreviations or chemical symbols utilized in medication orders shall be only those abbreviations or symbols that are customarily used in the practice of medicine and pharmacy or those on a list of approved abbreviations developed by the appropriate committee or representative of the facility.~~ New medication orders transmitted to the pharmacy for controlled substances, including Schedule II controlled substances, shall be in compliance with 657—Chapter 10, 657—Chapter 21, and federal regulations.

23.9(3) Who may transmit medication orders. An authorized prescriber or prescriber's agent ~~or any person who is employed by a long-term care facility and who is authorized by the facility's policies and procedures~~ may transmit to the ~~long-term care~~ pharmacy a medication order lawfully ordered by ~~a practitioner~~ an authorized to prescribe drugs and devices prescriber. An order transmitted by the prescriber's agent shall include the agent's first and last names and title. Specifically for the transmission of a controlled substance prescription, a member of the care facility staff is an agent of the prescriber

only if the prescriber maintains an office in the facility or there exists an agent agreement between the prescriber and the care facility staff member.

~~23.9(4) Influenza and pneumococcal vaccines. As authorized by federal law, a written or verbal patient-specific medication administration order shall not be required prior to administration to an adult patient of influenza and pneumococcal vaccines pursuant to physician-approved facility policy and after the patient has been assessed for contraindications. Administration shall be recorded in the patient's record. The facility shall submit to the provider pharmacy a listing of those residents or staff members who have been immunized utilizing vaccine from each vial supplied by the provider pharmacy.~~

ITEM 11. Rescind and reserve rule 657—23.10(124,155A).

ITEM 12. Amend rule 657—23.11(124,155A) as follows:

657—23.11(124,155A) Drugs dispensed—general requirements.

23.11(1) Labeling. All prescription containers, other than those dispensed pursuant to ~~rule 657—22.1(155A)~~ 657—Chapter 22, rule 657—23.13(124,155A), or rule 657—23.14(124,155A), shall be properly labeled in accordance with 657—subrule 6.10(1).

a. If a label change is required to reflect a change in directions, the ~~pharmacy~~ pharmacist shall be responsible for affixing the correct label to the container. ~~Long-term care~~ Care facility personnel shall not be ~~authorized~~ directed by the pharmacy to affix such a label to the drug container.

b. Direction change labels that notify ~~long-term~~ care facility personnel that a change in directions for the drug has taken place may be used and affixed to the container by facility personnel so as not to deface the original label.

23.11(2) Medication order required. Dispensing of all drugs to the facility shall be pursuant to a medication order for an individual resident except as provided in rules 657—23.5(124,155A) and 657—23.14(124,155A) ~~and in subrule 23.9(4).~~

23.11(3) Prescription containers. All prescription containers, ~~including but not limited to single unit, unit dose, and unit of issue containers~~ utilized for distribution within dispensing drugs to a long-term care facility, shall meet minimum requirements as established by the United States Pharmacopoeia and 657—Chapter 22. When applicable, light-resistant packaging shall be used.

23.11(4) Floor stock. Prescription drugs, as defined by Iowa Code section ~~455A.3(37)~~ 155A.3(38), shall not be floor-stocked in a ~~long-term~~ care facility except as provided in this subrule or in subrule 23.5(2). Bulk supplies of nonprescription drugs may be maintained as provided in subrule 23.13(3). Any pharmacy that utilizes a floor stock distribution system pursuant to this subrule shall develop and implement procedures to accurately establish proof of use of prescription drugs and shall maintain a perpetual inventory, whether by electronic or manual means, of all prescription drugs so dispensed. A floor stock distribution system for prescription drugs may be permitted only under the following circumstances:

a. and b. No change.

ITEM 13. Amend rule 657—23.13(124,155A) as follows:

657—23.13(124,155A) Labeling drugs under special circumstances.

23.13(1) ~~Insulin, ophthalmics, otic preparations, biologicals, and other injectables for individual patients~~ Drug products of insufficient size to accommodate pharmacy labeling. ~~These drugs~~ Drug products, such as insulin, ophthalmics, otic preparations, and injectables, that are of insufficient size to accommodate a full pharmacy label shall be dispensed with a label affixed to the immediate container showing at least the resident's name and location.

23.13(2) Legend solutions—irrigation and infusion. Legend irrigation solutions and infusion solutions supplied by a ~~licensed~~ pharmacy may be stored in the locked medication area of a ~~long-term~~ care facility provided that:

a. to c. No change.

d. The solution is stored appropriately after opening according to facility policy and manufacturer labeling.

23.13(3) Floor-stocked, nonprescription drug containers. All such nonprescription drugs intended for use within the facility shall be in appropriate containers and adequately labeled to identify, at a minimum, ~~brand name or generic drug~~ name and manufacturer, strength, lot number, and expiration date. ~~An internal code that centrally references manufacturer and lot number may be utilized.~~

23.13(4) and 23.13(5) No change.

ITEM 14. Amend rule 657—23.14(124,155A) as follows:

657—23.14(124,155A) Labeling of biologicals and other injectables supplied ~~Provision of drugs to a facility for immunization or screening programs.~~ Labeling of biologicals and other injectables supplied to a A pharmacy may provide drugs to be used in the care facility for a health immunization or ongoing screening program, such as influenza vaccine, tuberculin skin test, or hepatitis-B, ~~and intended for use in the facility, shall include the following information in addition to the manufacturer's label.~~

23.14(1) Labeling. The pharmacy label shall be affixed so as not to obscure the manufacturer's label and shall include the following information.

- ~~1. a.~~ Identification of pharmacy;
- ~~2. b.~~ Name of facility;
- ~~3. c.~~ Name of biological or drug;
- ~~4. d.~~ Route of administration when necessary for clarification;
- ~~5. e.~~ Strength of biological or drug;
- ~~6. f.~~ Auxiliary labels as needed;
- ~~7. g.~~ Date dispensed.

23.14(2) Influenza and pneumococcal vaccines. A patient-specific medication order shall not be required prior to administration to an adult patient of influenza or pneumococcal vaccines pursuant to physician-approved facility policy and after the patient has been assessed for contraindications.

23.14(3) Notification. The facility shall submit to the provider pharmacy a listing of those residents or staff members who have been immunized utilizing vaccine from each vial supplied by the provider pharmacy.

ITEM 15. Amend rule 657—23.15(124,155A) as follows:

657—23.15(124,155A) Return and reuse of drugs and devices. ~~Pharmacists and pharmacies~~ A pharmacy shall not accept from ~~residents or their agents~~ a patient or facility for reuse or resale any ~~drugs, prescribed drugs, chemicals, poisons or medical devices~~ drug or device unless, in the professional judgment of the pharmacist, the integrity of the ~~prescription drug or device~~ has not in any way been compromised. Under no circumstances shall a pharmacist accept from a patient or ~~patient's agent~~ facility any controlled substances ~~for return, exchange, or resale~~ except ~~to~~ for reuse by the same patient. Prescription drugs, excluding controlled substances, dispensed in a unit dose, unit of issue, or single unit packaging dispensing system pursuant to ~~657—22.1(155A)~~ 657—Chapter 22 may, however, be returned and reused as authorized in 657—subrule 22.1(6). No items of a personal contact nature which have been removed from the original package or container after ~~sale~~ dispensing shall be accepted for return, exchanged, or resold by any pharmacist.

ITEM 16. Rescind and reserve rule **657—23.16(124,155A).**

ITEM 17. Amend rule 657—23.17(124,155A) as follows:

657—23.17(124,155A) Accountability of controlled substances.

~~23.17(1) Proof of use.~~ Documentation of use Use of Schedule II controlled substances shall be ~~upon proof of use forms documented.~~ A committee or representative of the facility may also require that Schedule III, IV, or V controlled substances or any other drugs be accounted for on proof-of-use forms. ~~Proof of use forms~~ Documentation shall specify include at a minimum:

- ~~a. 1.~~ Name of drug;
- ~~b. 2.~~ Dose;
- ~~c. 3.~~ Name of ordering prescriber;

- ~~d.~~ 4. Name of resident;
- ~~e.~~ 5. Date and time of administration to resident;
- ~~f.~~ 6. Identification of individual administering;
- ~~g.~~ 7. Documentation of destruction, return to the pharmacy, or other disposition of all unused portions of single doses including the signatures of two individuals, at least one of whom is a licensed health care professional.

~~23.17(2) Container requirement. Any drug required to be counted and accounted for with proof-of-use forms shall be dispensed in a container that allows visual verification of quantity. Containers for solid oral doses must allow visual identification of individual doses and individual accountability.~~

ITEM 18. Rescind and reserve rule **657—23.18(124,155A)**.

ITEM 19. Amend rule 657—23.21(124,155A) as follows:

657—23.21(124,155A) Disposal of previously dispensed controlled substances. Controlled substances dispensed to a resident in a long-term care facility and subsequently requiring disposal due to discontinuance of the drug, death of the resident, or other reasons necessitating disposal shall be disposed of by one of the following methods. Controlled substances shall not be returned to a pharmacy for disposal.

~~23.21(1) Disposal in the facility. In facilities staffed by one or more persons licensed to administer drugs, a~~ A licensed health care professional (pharmacist, registered nurse, licensed practical nurse) may dispose of controlled substances in witness of one other responsible adult. The professional disposing of the drug shall prepare and maintain a readily retrievable record of the disposition which shall be clearly marked to indicate the disposition of resident drugs. The record shall include, at a minimum, the following:

- a. to f.* No change.

~~23.21(2) Authorized collection program within a facility. Registrants~~ Pharmacies registered with DEA ~~to administer an authorized collection program as authorized collectors~~ may install and ~~maintain~~ manage a collection receptacle in a long-term care facility for the purpose of disposal of ~~prescription drugs unwanted medications, including prescription drugs and controlled substances, pursuant to federal regulations, which can be found at <http://deaddiversion.usdoj.gov/drug-disposal/>.~~

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